MAR 16 2005

K050091

SECTION 6 – 510(k) SUMMARY

[Submitted pursuant to 21 CFR 807.87(h)]

1. Submitter Information

Submitter:	Direx Systems Corporation 11 Mercer Road Natick Business Park Natick, MA 01760
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Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	Duet SP
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter (ESWL)
Classification Name/ Product code:	78 LNS
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5990

3. Predicate Devices

Duet k023535, ***Duet SLO*** k041582, and TWINHEADS TH-101 k030346

4. Intended Use:

The intended use of the Duet SP Extracorporeal Shock Wave Lithotripter is the fragmentation of urinary tract stones (*i.e.* renal calyceal, renal pelvic, and upper ureteral stones).

5. Technological Characteristics:

This Duet includes a sonographic localization option that enables the use of ultrasound for positioning. The device has the same fundamental scientific technology and intended use as predicate devices.

6. Description

The *Duet* is a transportable Electrohydraulic Extracorporeal Shock Wave Lithotripter, which consists of a Shock Wave Generator (SWAG), a Motorized Floating Treatment Table (MFT), and control means.

7. Clinical Tests

No clinical tests were performed.

8. Conclusion

The Duet with the Sonographic Localization Option meets the requirements for a special 510(k) by the virtue of being a minor modification, which does not change the fundamental technology or reduce safety and effectiveness, of the Company's predicate devices: ***Duet*** *k023535 and* ***Duet SLO*** k041582.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Ms. Larisa Gershtein
Quality Assurance Manager
Direx Systems Corp.
11 Mercer Road
NATICK MA 01760

Re: K050091
Trade/Device Name: Duet SP Extracorporeal Shock Wave Lithotripter
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: February 17, 2005
Received: February 22, 2005

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050091

Device Name: Duet SP Extracorporeal Shock Wave Lithotripter

Indications for Use: The intended use of the Duet SP Extracorporeal Shock Wave Lithotripter is the fragmentation of urinary tract stones (i.e. renal calyceal, renal pelvic, and upper ureteral stones).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050091